

**REMARKS**

Upon entry of the present amendment, claims 23 and 24 will be canceled without prejudice or disclaimer of the subject matter recited therein; claims 21 and 22 will be amended, so that claims 3-16 and 21, 22 and 25-31 will remain pending.

The present amendment amends independent claims 21 and 22 to include subject matter recited in dependent claim 24. Moreover, dependent claims 23 and 24 have been canceled in view of the amendment of the independent claim 22. The present amendment is being made without expressing an agreement and/or acquiescence with the rejections of rejection, and is being made in an attempt to advance prosecution of the application by including subject matter from a dependent claim into each of the independent claims.

Accordingly, entry of the present amendment after final rejection is respectfully requested along with reconsideration of the rejections and allowance of the application in view of the following remarks.

**Response to Art Based Rejections and Indication of Allowable Subject Matter**

The following art based rejections are set forth in the Office Action.

(a) Claims 3-11, 13, 14, 16 and 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,416,744 to Robinson et al. (hereinafter "Robinson") in view of U.S. Patent No. 3,989,814 to Cordon et al. (hereinafter "Cordon").

(b) Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,416,744 to Robinson in view of U.S. Patent No. 3,989,814 to Cordon, and further in view of Gibbs et al., International Journal of Food Sciences and Nutrition 1999 (hereinafter "Gibbs").

(c) Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent

No. 6,416,744 to Robinson in view of U.S. Patent No. 3,989,814 to Cordon, and further in view of Rajaiah et al. (hereinafter "Rajaiah"), US 2003/0072841.

In response, Applicant submits that the documents used in the rejections of record do not teach or suggest Applicant's claimed subject matter whether taken alone or in combination. In this regard, Applicant submits that one having ordinary skill in the art would not have combined the documents in the manner set forth in the Office Action. Moreover, even if for the sake of argument the documents were combined, Applicant's claimed subject matter would not be at hand at least for the reasons set forth below.

As previously noted by Applicant, Robinson discloses a chewing gum composition for removing stains and whitening tooth enamel. The chewing gum disclosed by Robinson may contain from about 0.5 to about 3.0 wt% of silica particles as abrasive (column. 1, lines 59-64). Such a chewing gum composition is described as exhibiting low abrasiveness to tooth enamel, which is the protective layer of the tooth (column. 1, lines 10-11). Robinson thus purports to overcome the harshness of prior art chewing gums used for tooth-whitening purposes (column 1, lines 52-55). In fact, several examples of prior art chewing gum compositions are described in Robinson as containing mineral adjuvants such as calcium carbonates, calcined kaolin or zirconium silicate at high concentrations in the order of 10-40% by weight (column 1, lines 47-55).

It is apparent from a review of Robinson that a key technical objective of Robinson is to achieve a chewing gum composition that is both efficient in tooth-whitening and sufficiently mild towards the enamel layer **by avoiding mineral adjuvants at high concentrations by using his specifically disclosed silica particles. Calcium pyrophosphate is such a mineral adjuvant, and one having ordinary skill in the art would not have modified Robinson to**

**include a tooth whitening agent comprising calcium pyrophosphate present in an amount of between 5.5% and 7 % by weight of the composition, excluding any coating compositions, as recited in Applicant's claims.**

In fact, the examiner is reminded that beginning at column 2, line 41, Robinson goes into length describing the specifics of the silica used in his tooth whitening chewing gum by disclosing that:

The silica used to prepare the tooth whitening chewing gum compositions of the present invention is comprised of precipitated or colloidal particles of silica having an average particle size ranging from about 3 microns to about 12 microns, and more preferably between about 5 to about 10 microns and a pH range from 4 to 10 preferably 6 to 9 when measured as a 5% by 20 weight slurry.

The silica used to prepare the chewing gum compositions of the present invention is differentiated by means of its oil absorption value, having oil absorption value of less than 100 cc/100g, and preferably in the range of from 45 cc/100g silica to less than 70 cc/100g silica.

A silica particularly useful in the practice of the present invention is marketed under the trade designation Zeodent 105 by J. M Huber Co., Atlanta, Ga. 30327. An example of such silica is Zeodent DP105, a silica precipitate having a water content of 5% by weight averaging from about 7 to about 10 microns in diameter, having an Einlehner Hardness of 5, a BET surface area of 390 m<sup>2</sup>/g of silica, an oil absorption of less than 70 cm<sup>3</sup>/100g of silica. This silica exhibits low abrasiveness to tooth enamel.

The desired weight percentage of abrasive silica particles according to Robinson is from 0.5 to about 3.0% (column 1, lines 59-64). In addition to that, a further dentifrice abrasive such as tricalcium phosphate, sodium bicarbonate or other siliceous materials (other than silica particles) may be used (column 2, line 63 to column 3, line 3).

Thus, Robinson discloses that, "The silica abrasive can be used as the sole abrasive in preparing the chewing gum of the present invention or in combination with other known dentifrice abrasives or polishing agents including calcium carbonate, sodium bicarbonate,

sodium metaphosphate, potassium metaphosphate, tricalcium phosphate, dihydrated dicalcium phosphate, bentonite or other siliceous materials, or combinations thereof.

Following this disclosure, Robinson provides that the concentration of the abrasive silica, which would include the silica and other abrasive material is limited to at most about 5.0% by weight. In particular, Robinson discloses, at column 3, lines 4-7, that:

The total quantity of abrasive silica present in the chewing gum composition of the present invention is at a concentration of from about 0.2 to about 5.0% by weight, preferably from about 1.0% to about 3% by weight.

From the above, it is apparent that such optionally present additional abrasive is a minor constituent as compared to the silica particles. This is also evident from the above-noted paragraph which specifies that the total quantity of abrasive silica (i.e., silica particles plus additional siliceous material) is up to about 5.0% by weight, and preferably not greater than 3% by weight. In other words, the additional abrasive must not exceed about 2.0 wt% of the total composition. This also becomes apparent from the specific example of Robinson at Table I, in column 4, in which the silica, Zeodent DP105, is present at 2.00 wt% and additional abrasive, sodium bicarbonate, is present at 0.5 wt%.

Thus, in contrast to the assertions in the Final Office Action, it is readily apparent that the additional abrasive must not exceed about 2.0 wt% of the total composition. Moreover, calcium pyrophosphate is not one of the pyrophosphates that would be considered with respect to column 4, lines 11-14 of Robinson.

The subject-matter of Applicant's independent claims 21 and 22 thus patentably differs from Robinson in at least the recitation of the tooth whitening agent comprising calcium pyrophosphate present in an amount of between 5.5% and 7% by weight of the composition, excluding any coating compositions.

The deficiencies of Robinson are not overcome by the other documents used in the rejections. As previously noted by Applicant, Cordon relates to a dentifrice, i.e., a pharmaceutical compound used in conjunction with the toothbrush to clean and polish the teeth, such as toothpaste or dental creams (column 1, lines 24-26; and column 3, lines 12-19). The dentifrice contains a non-toxic zinc compound and calcium pyrophosphate as abrasive (column 1, lines 58-63). **The amount of calcium pyrophosphate is at least 7.5% by weight, more preferably about 20-75% by weight of the dentifrice (col. 1, lines 14-23).**

The skilled person would not have combined the disclosures of Robinson and Cordon as the disclosure of Robinson relating to the concentration of silica abrasive would not lead one having ordinary skill in the art to add calcium pyrophosphate let alone calcium pyrophosphate in the amount recited in Applicant's claims in any composition of Robinson. Thus, one having ordinary skill in the art would not have considered adding between 5.5% and 7% wt% of calcium pyrophosphate to the chewing gum composition of Robinson.

Even if for the sake of argument one having ordinary skill in the art would have included calcium pyrophosphate as part of the silica abrasive in Robinson, at most calcium pyrophosphate would have been added as minor additional constituent not exceeding 2 wt% of the chewing gum composition of Robinson. One having ordinary skill in the art would be deterred from using a higher amount of calcium pyrophosphate than 2 wt% in Robinson due to the disclosed enamel aggressiveness of mineral adjuvants in Robinson. Moreover, one having ordinary skill in the art would not replace the silica particles of the chewing gum of Robinson with an equal amount of calcium pyrophosphate since the silica particles are central to the mild abrasive nature of the chewing gum disclosed by Robinson. Accordingly, the combination of documents asserted in the rejections would essentially destroy the desired objectives of Robinson.

**In contrast, the Final Office Action contends that one skilled in this art would have understood that the various features of Robinson and Cordon would have been combined to obtain the expected benefits, i.e., the superior cleaning and polishing characteristics of calcium pyrophosphate in an amount of at least about 7.5% by weight. Accordingly, even if for the sake of argument, the disclosure were combined, Applicant's recited subject matter would not be at hand, because the combination of references does not teach or suggest at least Applicant's recited tooth whitening agent comprising calcium pyrophosphate present in an amount of between 5.5% and 7 % by weight of the composition, excluding any coating compositions.**

In addition, Applicant again notes that Cordon discloses calcium pyrophosphate as an abrasive for toothpastes and dental creams, but not for chewing gum. One having ordinary skill in the art would have no reasonable expectation of success for using calcium pyrophosphate in a chewing gum composition following the disclosure of Cordon since the physical application of toothpaste versus chewing gum is considerably different. One having ordinary skill in the art would not have a reason to consider the Cordon's disclosure in connection with Robinson.

This is even more so as the toothpaste of Cordon may comprise up to 75 wt% of calcium pyrophosphate. This is also confirmed by prior art chewing gums containing mineral adjuncts as abrasive materials. Such prior art chewing gums require considerably higher amounts of such polishing agents for producing a tooth-whitening effect than what is claimed in the present application. It is a well-established prejudice of the prior art that weight percentages in the order of 10-40 % are required to this end (see, for example, Robinson, column 1, lines 47-55).

Thus, one having ordinary skill in the art is discouraged from adding between 5.5 wt% and 7 wt% of calcium pyrophosphate to the chewing gum composition of Robinson for at least

these two independent reasons. Robinson teaches that such an amount of mineral-derived abrasive material is highly undesirable due to its aggressiveness towards enamel. In addition, both Robinson and Cordon teach that in order to be effective, chewing gum compositions must be supplied with considerably higher amounts of such mineral-derived abrasive materials.

As disclosed on page 2, lines 17-22, of Applicant's originally filed specification, calcium pyrophosphate is described in the prior art as one of the least effective abrasives as compared to other mineral-derived abrasive materials. Accordingly, the finding of Applicant that amounts of 3-8 wt%, more preferably 5.5-7 wt% of calcium pyrophosphate in a chewing gum or confectionary composition are surprisingly effective in terms of tooth-whitening is certainly non-obvious for a number of compelling reasons.

The Final Office Action asserts that this finding is not surprising apparently as the use of calcium pyrophosphate is known. However, the Final Office Action does not address the surprising results associated with Applicant's recited amounts of calcium pyrophosphate.

Applicant further once again submits that each of the dependent claims is patentable over the prior art used in the rejections at least for the reasons set forth above, and for the further recitations set forth in each claim. In view of the arguments presented above, it is expected that the rejections of record will be withdrawn in the next communication from the Patent and Trademark Office. Accordingly, Applicant is not providing further detailed arguments against the rejections of each dependent claim at the present time, but preserves the right to submit more detailed arguments in the event that the rejections are not withdrawn and/or any new ground of rejection is instituted. However, Applicant notes that Gibbs is only used in the rejection of claim 12 in an attempt to try and establish the obviousness of encapsulating at least one additive of Robinson, and Rajaiah is only used in the rejection of claim 15 in an attempt to try and establish

the obviousness of adding Vitamin C to the composition of Robinson. Thus, whether or not one having ordinary skill in the art would have looked to the disclosures of Gibbs or Rajaiah to modify Robinson combined with Cordon, which Applicant submits would not have been a proper combination, Applicant's claimed subject matter would not present at least for the reasons set forth above.

Accordingly, withdrawal of the rejections of record with allowance of the application is respectfully requested.

### CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,  
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